

REMARKS

In the Office Action, the Examiner rejected claims 1-7 and 9-28. For at least the reasons set forth below, however, Applicants respectfully submit that all of pending claims 1-7 and 9-28 are allowable in their present forms. Consequently, Applicants respectfully request reconsideration of the above-referenced application in view of the following remarks. Particularly, Applicants refer the Examiner to pages 11-14 of the present communication, which addresses the Examiner's "Response to Arguments" section of the Office Action mailed September 14, 2006, noting both the legal and factual shortcomings of the present rejection, as well as an apparent mischaracterization or misunderstanding of the present claims.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

In the Office Action, the Examiner rejected claims 1-7 and 9-28 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

Legal Precedent

Regarding the enablement requirement, the Examiner has the initial burden to establish a *reasonable basis* to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The test for enablement, as set forth by the Supreme Court, is whether the experimentation needed to practice the invention is undue or unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991). The *undue experimentation* test essentially evaluates whether one of reasonable skill in the art can make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). As long as the specification discloses at least one method for making and using the claimed invention that bears a *reasonable correlation* to the entire scope of

the claim, then the enablement requirement of section 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970).

Deficiencies of the Rejection

In the Office Action, the Examiner specifically stated:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. Claim 1 includes the limitation “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment component”. Similar limitations occur in each of independent claims 15, 23 and 28, and are incorporated into the dependent claims through their dependencies. The specification fails to teach how the operational parameters can [be] used to make such identifications. Although the specification mentions several operational parameters that may be used in the analysis, it does not show what types of operators activities may cause an effect on these parameters or how the analysis is to actually be performed. Deriving such algorithms and determining how each parameter is [a]ffected by operators’ activities would require undue experimentation on the part of one of ordinary skill in the art. Further, claim 5 recites that the data is representative of individual operators utilizing the equipment components. The specification makes no mention as to how the specific user of a piece of biomedical equipment is tracked or determined.

Office Action mailed September 14, 2006, page 2. Applicants respectfully submit, however, that one of ordinary skill in the art would be able to practice the presently disclosed invention based on the specification of the instant application, coupled with information known in the art, without undue experimentation.

As previously noted, the present application is generally directed to identifying potential training needs of service personnel. Application, page 1, lines 7-9. Among other things, Applicants have disclosed a service system 10 that facilitates identification of certain training needs based on various data. *See id.* at page 4, lines 15-17; FIG. 1. In

one embodiment, the system 10 includes various hardware components, such as databases 60, clients 64 and servers 66, and various modules for collecting, storing, and analyzing data, such as data collection/storage/association sequence 74, population data sequence 76, and analysis module 118. *See id.* at page 7, lines 6-21; page 10, lines 19-22; FIGS. 1, 2, and 4. In an exemplary embodiment, specific data obtained from a specific institution may be analyzed by comparison to a benchmark derived from other institutions or groups of such institutions. *See id.* at page 9, line 9 – page 10, line 4; page 10, line 23 – page 11, line 10. Analysis of the data may also include determination of utilization parameters, identification of error codes, trends, and so forth, and also identification of trends in the data over time. *See id.* at page 12, line 28 – page 13, line 6. In this exemplary embodiment, training needs may be identified in areas in which the specific institutional data deviates substantially from the benchmark data, or training needs may be identifiable to one skilled in the art based on logged errors, downtimes, and service or procedural inquiries. *See id.* at page 13, lines 8-16; page 14, lines 23 – page 15, line 11.

By way of example, with respect to a hypothetical system having a CD-ROM drive, data indicating repeated replacement of the CD-ROM drive due to user error may suggest that the user needs to be trained on the proper use of a CD-ROM drive. Although development of an actual implementation of the present claims may require various implementation-specific decisions to achieve certain goals (and may be more complex than the rudimentary example provided immediately above), Applicants respectfully submit that such development would be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill in the art having the benefit of this disclosure, and would not require undue experimentation. For at least these reasons, Applicants respectfully submit that the subject matter of the pending claims is enabled, and that the present rejection is improper.

Response to Arguments

Applicants appreciate the Examiner's consideration of the exemplary portions of the specification cited by Applicants in the previous response. Applicants, however, believe that the Examiner's remarks in the Office Action mailed September 14, 2006, are based on an unintentional, yet fundamental, misunderstanding of the present claims and Applicants' previous remarks, which has lead to the untenable rejection at issue. Because the present rejection is improper, Applicants are filing a Notice of Appeal concurrently with this Response to advance this case toward issuance. However, as the present remarks are intended to correct this misunderstanding, Applicants again kindly invite the Examiner to contact the undersigned to discuss the instant claims and their enablement by the present patent application.

As an initial matter, Applicants note the unnecessarily lengthy examination process which Applicants have endured in the present case. Particularly, prior to examination by the current examiner, the present application had already undergone substantial examination by a different examiner. In fact, the file history includes four Office Actions issued by the previous examiner, which were variously approved by a primary examiner and *two* different supervisory examiners, and *two* Appeal Briefs prior to examination by the present examiner. Although previously examined and reviewed by at least four different examiners, the present claims were never rejected under 35 U.S.C. § 112, first paragraph, and one may infer that these examiners believed that the present claims were enabled. In other words, although the present examiner is no less than the *fifth* examiner to review this case, she is the first (and only) examiner to suggest that the present claims are not enabled. Further, the Manual of Patent Examining Procedure states that:

When an examiner is assigned to act on an application which has received one or more actions by some other examiner, full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general the second examiner should not take an entirely new approach to the application or attempt

to reorient the point of view of the previous examiner, or
make a new search in the mere hope of finding something.

M.P.E.P. § 704.01; *see Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 57 U.S.P.Q.2d 1449, 1499-50 (D. Mass. 2001); M.P.E.P. § 706.04. While Applicants believe the present rejection is also improper for a number of substantive reasons, Applicants respectfully submit that the present action fails to give *any* faith or credit to the actions of the previous examiners (let alone *full* faith and credit) with respect to enablement, is inconsistent with the numerous actions by the previous examiners, and is only adding to the undue delay endured by Applicants in the examination of the present case.

With respect to the substance of the present enablement rejection, in referring to a cited passage of the specification (page 14, line 23 – page 15, line 11), the Examiner stated that:

This citation does not show how the data is analyzed, correlated or used to identify “at least one operational parameter affected by operator activities with the equipment component”, as is recited in the claim. Or how such an identification is then used to determine a training need based on the analyzed data. It is unclear how data relating to logged errors, downtimes, and service and procedural inquiries equity to use [*sic*] parameters affected by operator activities with the equipment component, when related to the use of biomedical equipment.

Office Action mailed September 14, 2006, page 4. Applicants respectfully submit that, despite the Examiner’s apparent confusion, one of ordinary skill in the art upon reading the instant disclosure would immediately appreciate that *operational parameters such as the disclosed “logged errors, downtimes, service and procedural inquiries,” and the like may result from operator activities of the biomedical equipment components*. Further, through analysis of such operational parameters (*e.g.*, repeated logged errors, procedural inquiries, or the like), one of ordinary skill in the art would be able to determine the existence of training needs with respect to the equipment components.

As will be appreciated by those of ordinary skill in the art, the level of specificity of the training need may depend upon the quantity and type of the identified operational parameters. For instance, logged errors may specifically indicate the exact nature and cause of errors, or may only indicate that errors have occurred. In the case of the latter, one of ordinary skill in the art having benefit of the present disclosure would be able to correlate the occurrence of a large number of errors in one system (which may be measured in comparison to the benchmark data disclosed in the present application) with the existence of a general training need with respect to users of that system. Conversely, with respect to the former, one of ordinary skill in the art would be able to correlate more specific logged errors with more particular training needs. Additionally, with respect to enablement of the subject matter of claim 5, one of even routine skill in the art would instantly appreciate that the use of a login procedure would allow tracking and analysis of individual operators utilizing the equipment.

Finally, Applicants respectfully submit that, at a minimum, a *prima facie* case with respect to non-enablement requires the Examiner to conduct a *factual* analysis and provide sufficient *evidence* that a disclosure does not satisfy the enablement requirement and that any necessary experimentation is “undue.” See M.P.E.P. § 2164 *et seq.* The rejection set forth in the Office Action, however, fails to make such an analysis or provide such evidence. In essence, the rejection is conclusory – alleging that undue experimentation would be required of one of ordinary skill in the art, without *any* analysis or evidence with respect to the level of one of ordinary skill or explanation why any experimentation would be “undue.” Applicants remind the Examiner that “[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. M.P.E.P. § 2164.01; *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int’l Trade Comm’n 1983), *aff’d. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985). Applicants respectfully submit that the present rejection, which lacks legally sufficient analysis and evidence, cannot establish a *prima facie* case of non-enablement. Further, Applicants again point out that although development of an

actual implementation of the present claims may require various implementation-specific decisions to achieve certain goals, such development would be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill in the art having the benefit of this disclosure, and would not require undue experimentation.

For at least the reasons provided above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, and allowance of claims 1-7 and 9-28.

Conclusion

In view of the remarks set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes certain amendments are necessary to clarify the present claims or if the Examiner wishes to resolve any other issues by way of a telephone conference, the Examiner is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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